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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/447,227 | 11/22/1999 | MARK C. SHULTS | MARKWELL-040 | 3546 |

20995 7590 11/28/2003

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EXAMINER

NASSER, ROBERT L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3736

DATE MAILED: 11/28/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/447,227

Applicant(s)

SHULTS ET AL.

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,22,24 and 28-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-42,49 and 55 is/are allowed.
- 6) ☒ Claim(s) 21-22, 24, 28-33, 43-48, 50-54 is/are rejected.
- 7) ☒ Claim(s) 34-37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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In reviewing applicant's response, the arguments were found convincing. Accordingly, the finality of the previous rejection is hereby withdrawn and the following new final rejection entered in its place.

The examiner further notes that upon further review of the application, the present invention is a divisional of 08/811473, filed 3/4/1997. Accordingly, the effective date of the current claims is 3/4/1997. This data is not in the patent office computer and was previously overlooked by the examiner.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 22, 24, 28-33, and 43-48 are rejected under 35 U.S.C. 103(a) as being obvious over Blubaugh Jr. et al et al in view of Picha. Blubaugh Jr. et al shows a glucose sensor for subcutaneous, but not intra-vascular implantation, including a housing 10, and a sensor means 16 where the device a first layer 12 (second domain) that is impermeable to microphages and a sensing membrane 14 containing glucose oxidase, where the layer 12 is more distal to the housing than layer 14. It does not have the first domain, recited in the claims. However, Picha teaches that providing an outer layer 14 to promote tissue ingrowth, i.e. an angiogenic layer, extends the useable life of a sensor. Hence, it would have been obvious to modify Blubaugh Jr. et al to use such

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an outer layer, to extend its useable life. The examiner notes that Blubaugh Jr. et al Schulman does not specifically say how long it can function inside the body. However, it is the examiner's position that the use of the outer layer of Picha allows it to be used as long as the time periods claimed. The examiner notes that Blubaugh Jr. further transmits the data out side of the body wirelessly (see column 9, lines 31-40). The examiner further notes that the combination sensor would have an interface tip. With respect to claim 29, Blubaugh calibrates the device after implantation (see column 10, lines 26-34).

Claims 50-54 are rejected under 35 U.S.C. 103(a) as being obvious of Blubaugh Jr. et al in view of Picha, as applied to claims 21, 22, 24, 28-33, and 43-48 and Ward et al 6466810. The combination of Blubaugh Jr et al and Picha does not have a proximal electrolytic layer. Ward teaches a layer 107 that functions to increase the response time of the sensor. Hence, it would have been obvious to modify Blubaugh Jr. et al to use such an electrolytic layer, to increase the response time of the sensor.

Claims 34-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. These claims define over the art in that none of the art shows a capsular attachment layer or an angiogenic layer in addition to a layer that supports tissue ingrowth, e.g. the first domain.

Claims 38-42, 49, and 55 are allowable. These claims define over the art in that none of the art shows a vascularization promotion layer in addition to the first domain, a tissue ingrowth allowing domain.

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Applicant's arguments filed 11/5/2003 have been fully considered but they are deemed moot in view of the new grounds of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

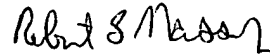
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on MAXIFLEX.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
November 17, 2003

ROBERT L. NASSER
PRIMARY EXAMINER